

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

ADAM KANUSZEWSKI and
ASHLEY KANUSZEWSKI as parent
guardians and next friend to their minor
children D.W.L., R.F.K., and C.K.K.;
SHANNON LAPORTE as parent-
guardian and next friend to her minor
children, M.T.L. and E.M.O.; and
LYNETTE WIEGAND, as parent-
guardian and next friend to her minor
children, L.R.W., C.J.W, H.J.W., and
M.L.W.,

Case. No. 18-10472-TLL-PTM

Honorable Thomas L. Ludington
Mag. Judge Patricia T. Morris

Plaintiffs.

v.

MICHIGAN DEPARTMENT OF
HEALTH AND HUMAN SERVICES;
NICK LYONS, sued in his official and
individual capacities; DR. SANDIP
SHAH, sued in his official and
individual capacities; DR. SARAH
LYON-CALLO, sued in her official and
individual capacities; MARY KLEYN,
sued in her official and individual
capacities; MICHIGAN NEONATAL
BIOBANK, INC also known as
MICHIGAN NEONATAL
BIOREPOSITORY; DR. ANTONIO
YANCEY, sued in his official and
individual capacities,

DEFENDANTS MICHIGAN
NEONATAL BIOBANK, INC. AND
DR. ANTONIO YANCEY'S
REPLY BRIEF

Defendants.

Plaintiffs' Response does nothing to undercut the fundamental fact that Michigan's newborn blood screening program is constitutional; that the Plaintiffs lack standing as they have not alleged actual, non-speculative harm; and that the two main cases Plaintiffs rely on to support their claim, *Cruzan* and *Birchfield*, do not actually support their position. Further, while not dispositive, it is worth noting that similar matters have been litigated previously in several different states, and the courts, both state and federal, have come down in support of permitting newborn blood screening as a valuable public health tool. Plaintiffs' case should be dismissed with prejudice.

I. PLAINTIFFS HAVE NOT REBUTTED THE ALLEGATION THAT THEY LACK STANDING

As to the Biobank Defendants, Plaintiffs have failed to demonstrate standing. The minor children in this case fall into three (3) distinct groups: those born prior to 2010 and subject to MDHHS's opt-out provisions regarding dried blood spot (DBS) cards, those born after 2010 and subject to the opt-in requirements who have opted-in, and those born after 2010 and subject to the opt-in requirements who have not opted in. Each group fails to show standing. As the Motion to Dismiss filed by the State Defendants shows, at least some of the parents of the minor children opted in to allowing the DBS cards to be used for research. They have waived a claim for ongoing harm. For all groups, there is no threat of

ongoing harm and no allegation in the First Amended Complaint that the Parents have attempted to have the DBS cards destroyed and been rebuffed.

As Plaintiffs' First Amended Complaint points out in Exhibit B, MDHHS policy reads in relevant part:

Parents, legal guardians of, and/or persons from whom the specimen was collected after reaching the age of majority, ***may request that their specimen not be used for any research***, by contacting DCH by telephone or mail. Parents, legal guardians of, and/or persons from whom the specimen was collected after reaching the age of majority, ***may request that their specimen be destroyed ...***

(Complaint, Ex. B, emphasis supplied).

Accordingly, there is a known process for having the DBS cards destroyed, but Plaintiffs' do not claim to have attempted to have the minor children's DBS cards destroyed, let alone had such a request denied.

As noted by the U.S. District Court of the Western District of Texas in a similar case,

Plaintiffs' alleged ongoing harm is the *possible* expropriation of their children's previously taken blood by its release to third parties and those third parties' retention and use of the blood specimens. ... But there is no allegation that, at the time Plaintiffs filed this suit, they had even requested information about the fate of their children's blood specimens, much less that they had done so and were refused. Nor had they requested that the blood specimens be destroyed and been informed that this was not possible due to their release to third parties. Thus, their informational claims were not ripe at the time they filed suit and/or they lacked standing because they had suffered no injury in fact with regard to the denial of information or the denial of a request for destruction.

Higgins v. Tex. Dep't of Health Servs., 801 F.Supp.2d 541 (W.D. Tex, 2011). *See also, Doe v. Adams*, 53 N.E.3d 483, (Ind. 2016) (upholding trial court's dismissal of Plaintiff's claim for lack of standing when the only harm was fear of potential misuses of DBS cards) (Ex. 1).

In this case, much as in *Higgins*, there is no ongoing future harm, there is no injury, and therefore there is no standing.

II. *CRUZAN* DOES NOT SUPPORT PLAINTIFFS' POSITION

Plaintiff takes the position that *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261 (1990) supports their contention that Michigan's newborn screening program violates their civil rights. *Cruzan* does not support this position. *Cruzan* stated that "[t]he principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions", but in the next sentence it upheld *Jacobson v. Massachusetts*, noting that "the Court balanced an individual's liberty interest in declining an unwanted smallpox vaccine against the State's interest in preventing disease." *Cruzan*, at 278. As *Cruzan* itself noted, "determining that a person has a 'liberty' interest' under the Due Process Clause does not end the inquiry; 'whether respondent's constitutional rights have been violated must be determined by balancing his liberty interest against the relevant state interests.'" *Cruzan*, at 279.

The blood draws taken from newborns to screen for congenital disease or disorders is recognized as a valid governmental concern. As even the Plaintiffs admit, only five or six drops of blood are drawn, and once the blood is drawn, the

infants are screened for over 50 congenital conditions. This is performed by “A health professional in charge of the care of a newborn infant or, if none, the health professional in charge at the birth of an infant.” MCL 333.5431(1). If the results of a test comes back “positive, the results shall be reported to the infant’s parents, guardian, or person *in loco parentis*.” MCL 333.5431(3). The infant’s parents can then determine what course of action to take regarding the infant’s health. The statute ***does not*** mandate any course of treatment, and thus does not run afoul of *Cruzan* or any other law regarding the right to self-determination.

III. INFORMED CONSENT IS NOT REQUIRED TO DRAW BLOOD FOR NEWBORN SCREENING

“In Michigan, the common law prevails except as abrogated by the Constitution, the Legislature, or this Court. Mich. Const. 1963, Art. 3, §7; *People v Aaron*, 409 Mich 672, 722-723; 299 NW2d 304 (1980); *People v Duffield*, 387 Mich 300, 308; 197 NW2d 25 (1972).” *People v Stevenson*, 416 Mich 383 (1982). Similarly, Michigan recognizes and adheres to the common-law right to be free from nonconsensual physical invasions and the corollary doctrine of informed consent. *See, e.g., In re Rosebush*, 195 Mich App 675 (1992). However, Michigan law also holds that:

It is axiomatic that the Legislature has the authority to abrogate the common law. *Hoerstman Gen Contracting, Inc v Hahn*, 474 Mich. 66, 74; 711 N.W.2d 340 (2006). Further, if a statutory provision and the common law conflict, the common law must yield. *Pulver v.*

Dundee Cement Co, 445 Mich. 68, 75 n 8; 515 N.W.2d 728 (1994). Accordingly, this Court has observed:

In general, where comprehensive legislation prescribes in detail a course of conduct to pursue and the parties and things affected, and designates specific limitations and exceptions, the Legislature will be found to have intended that the statute supersede and replace the common law dealing with the subject matter. [*Hoerstman Gen Contracting*, *supra* at 74, quoting *Millross v Plum Hollow Golf Club*, 429 Mich. 178, 183; 413 N.W.2d 17 (1987), citing 2A Sands, Sutherland Statutory Construction (4th ed), § 50.05, pp 440-441]. *Trentadue v. Gorton*, 479 Mich. 378 (2007).

The Michigan Supreme Court has held that “[t]his Court has previously recognized that the Legislature’s constitutional power to change the common law authorizes it to extinguish common-law rights of action.” *O'Brien v. Hazelet & Erdal*, 410 Mich. 1 (1980).

The law governing screening of newborns for chronic and congenital conditions specifically states that informed consent is not required for the test, abrogating that common-law requirement. MCL 333.5431(2) states: “The informed consent requirements of sections 17020 and 17520 do not apply to the tests required under subsection (1). The tests required under subsection (1) shall be administered and reported within a time and under conditions prescribed by the department. The department may require that the tests be performed by the department.” MCL 333.5431(3). Thus, the Michigan state legislature has, as far as newborn screening is concerned, abrogated the common-law requirement of informed consent.

IV. *BIRCHFIELD* IS NOT RELEVANT TO THIS CASE.

Plaintiffs cite *Birchfield v. North Dakota*, 579 U.S. ____ (2016) to support their claim that the drawing of blood from newborns is a Fourth Amendment violation in the context of medical testing. Further, Plaintiffs express shock that *Birchfield* was not even addressed in the Biobank's original Motion to Dismiss. The reason is simple: *Birchfield* deals with blood draws as searches incident to a lawful arrest, a criminal procedure context. *Birchfield* is completely inapplicable to this matter, and to the extent Plaintiffs have relied on it, they have done so out of context to support their otherwise baseless position.

All of the discussion of blood tests in *Birchfield*, including the language Plaintiffs rely on regarding how they require piercing the skin, relates to the criminal search context. The *Birchfield* decision also points out that "It is true, of course, that people voluntarily submit to the taking of blood samples as part of a physical examination and the process involves little pain or risk." *Birchfield* at ***40. *Birchfield* mentions this to give the issue in question context and to point out that blood draws are more invasive than blowing in a tube, i.e., the breath test given to drunk drivers. The context surrounding *Birchfield* matters, and to ignore the fact that *Birchfield* is a criminal case that holds exigent circumstances are insufficient to permit a blood draw of a suspected drunk driver is to ignore the limited import of that decision, for the sake of a soundbite.

V. CONCLUSION

Plaintiffs' First Amended Complaint against Michigan Neonatal Biobank, Inc. and Dr. Antonio Yancey fails as a matter of law and should be dismissed. Plaintiffs' Response does nothing to demonstrate that they have a valid cause of action as a matter of law, and indeed, filings by the State indicate that not only do the Plaintiffs' not have a cause of action, the Parents were aware of the policy and in some cases consented to the use of the dried bloods spots for research purposes. Newborn screening is a valid exercise of the state's public health authority and has been upheld against multiple challenges to it nationwide. Plaintiffs themselves acknowledge that the extent of the taking of blood from newborns is extremely limited.

For the reasons stated, the claims against MICHIGAN NEONATAL BIOBANK, INC. and DR. ANTONIO YANCEY should be dismissed in their entirety.

Respectfully Submitted,

PEAR SPERLING EGGAN & DANIELS, P.C.

Dated: July 26, 2018

BY: /s/ Jeremy C. Kennedy
Jeremy C. Kennedy (P64821)
Attorneys for Defendant Michigan Neonatal
BioBank, Inc. and Dr. Antonio Yancey in his
professional capacity only

CERTIFICATE OF SERVICE

I hereby certify that on July 27, 2018, I caused the electronic filing of the foregoing paper with the Clerk of the Court using the ECF system which will send notification of such filing to all attorneys and parties who are on the list to receive notifications for this case.

/s/ Jeremy C. Kennedy

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